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EXAMINER				
BARHAM, BETHANY P				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary

Application No.

10/510,126

Applicant(s)

PEREZ-CAMARGO ET AL.

Examiner

BETHANY BARHAM

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-53.55 and 58-71 is/are pending in the application.
- 4a) Of the above claim(s) 38-47 and 61-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-53.55 and 58-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Summary

Applicant is reminded that the office has not received IDS as of this date. Receipt of Applicant's Response and claim amendments filed on 1/8/09 are acknowledged. Claims 38-53, 55 and 58-71 are pending. Claims 38-47 and 61-71 remain withdrawn. Claims 48-53, 55 and 58-60 are rejected.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 48 and all dependent therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims contain the language "pancreatic extract" which is indefinite. What is a pancreatic extract? Further, Applicant's Example 2 teaches that the preferred pancreatic function promoter is taurine, is this also a pancreatic extract? Applicant has not properly defined the term "pancreatic extract" in the instant specification. The claims are therefore indefinite.

Claims 55, 58 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims contain the language "wherein the component" which is indefinite. Which component? Applicant has amended the independent claim 48 to specify "a pancreatic function promoter and an, intestinal mucosa function-promoter in an amount effective to maintain, promote or enhance the capacity of the pet to digest lipid, wherein the intestinal mucosa function-promoter comprises- an omega-3 fatty acid derived from fish oils, and wherein the pancreatic function promoter is a pancreatic extract", so the intestinal mucosa function promoter cannot be whey protein since claim 48 requires it to be fish oil. This is confusing and Applicant needs to clarify, is there a secondary intestinal mucosa function promoter? The claims are therefore indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 48-50, 52-53 and 58 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,369,252 ('252).

The instant claims are drawn to a nutrition management regimen comprising a dietary component for feeding regularly, according to predetermined directions, to a pet animal, the dietary component comprising a pancreatic function promoter and an, intestinal mucosa function-promoter in an amount effective to maintain, promote or enhance the capacity of the pet to digest lipid, wherein the intestinal mucosa function-promoter comprises- an omega-3 fatty acid derived from fish oils, and wherein the pancreatic function promoter is a pancreatic extract.

Example 6 and Table 21 of '252 teach a formulation of SL which comprises lipase and fish oil along with tricaprylin and the formulation was found to increase the immune system function after being fed to animals in Example 7 along with vitamins/minerals (which according to the instant specification are liver promoters, pg. 13, line 2).

Instant claims 48-50 are taught since the formulation comprises two lipases (the instant specification defines a pancreatic extract to be a lipase pg. 12, lines 1-3), and fish oil (Example 6 and col. 9, lines 54-56).

Instant claim 49 and 52-53 are taught since the Example 6 of '252 teaches including vitamins/minerals (which are liver promoters).

Claims 48-53, 55 and 58-60 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1 048 226 ('226).

The instant claims are described above.

Example 1 of '226 teaches a formulation comprising whey protein concentrate, pancreatin (a known pancreatic extract or lipase), fish oil, soya oil, vitamins/minerals and various amino acids including glutamic acid, cystine and glycine (which are glutathione promoters).

Instant claim 48 is taught since Example 1 teaches a formula comprising fish oil and pancreatin.

Instant claims 49-53 are taught since Example 1 also teaches a buffering solution (a secondary pancreatic promoter) and additionally vitamins/minerals and amino acids glutamic acid, cystine and glycine (which are glutathione promoters or a liver promoter).

Instant claims 55 and 58-60 are taught since the composition of Example 1 contains whey protein concentrate and fish oil.

Claim 48 and 58-59 are rejected under 35 U.S.C. 102(a) or 102(e) as being anticipated by US 6,228,367 ('367).

The instant claims are described above.

'367 claims in claim 1 a food supplement formulation of fish oil and lipase (the instant specification defines a pancreatic extract to be a lipase pg. 12, lines 1-3)

(abstract, claim 1). The supplement of '367 improves bodily functions including fat metabolism, etc (col. 2, lines 26-30).

Fish oil of '367 and instant claim 48 has a specific fatty acid profile and therefore would meet the limitations of claims 58-59.

Claims 48-52, and 58-59 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,576,667 ('667).

The instant claims are described above.

'667 Example 7 teaches a composition comprising lipase and an emulsifier mixed with fish oil.

Instant claim 48 and 58-59 are taught since Example 7 teaches a formula comprising fish oil and lipase. Fish oil of '667 and instant claim 48 has a specific fatty acid profile and therefore would meet the limitations of claims 58-59.

Instant claims 49-52 are taught since Example 7 also teaches lipase and additionally an emulsifier (or a liver promoter).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48-53, 55 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,471,999 ('999) in view of JP 408038063 ('063) or US 2001/0051206 ('206).

The instant claims are described above.

- '999 teach a pet milk powder as nutritional milk that results in reduced gastrointestinal intolerance (abstract). '999 teaches that the milk powder when administered in an effective amount with the nutritional composition reduces gastrointestinal intolerance and that it may further comprise one or more lipid source, protein source, vitamins and minerals, and teaches a specific aspect which comprises lactose (of micro-organism origin), lactase, taurine, arginine and choline (claims 1-9; col. 2, lines 9-lines 26). (Applicant's instant specification teaches that taurine is a pancreatic promoter instant Example 2).
- '999 teaches omega fatty acids such as soybean and rapeseed oil and in Examples 1-2 (col. 3, lines 15-20).
- '999 teaches including an alkali in the milk-based powder, which slows the pH, drop in the gastrointestinal tract (col. 2, lines 53-55). '999 teaches that a protein source of whey protein and further supplemented with taurine and a probiotic micro-organism which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40) (meets the limitations of claims 48-51 a first and second pancreatic promoter and further claims 52-53, 55, 58-60 since whey protein, omega-3 and taurine are all taught).

- '999 teaches chicory fibers, inulin, fructooligosaccharides with the probiotic micro-organism have a symbiotic relationship for promoting beneficial effects (col. 4, lines 9-14) (according to the limitations of claims 49-50).
- '999 teaches that the amount of nutritional composition is to be fed to a mammal each day depends of factors such as age, type of mammal (dogs and cats), and other nutritional sources (col. 4, lines 25-36).
- Examples 1 and 2 teach mixing the milk powder, galactosidase (lactase amino), vitamins, minerals, and soybean oil, and adding water to provide nutritional supplement to dogs and puppies or cats.
- '999 teaches that a protein source of whey protein and further supplemented with taurine and a probiotic micro-organism which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40) (according to the limitations of claims 55 and 58-60).
- '999 does not teach omega fatty acids derived from fish oil.
- '063 teaches a pet food composition with omega fatty acids, preferably fish oil (abstract).
- '206 teaches a pet food composition including omega fatty acids such as flaxseed and fish oil (abstract, Example 1 and Table 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a known omega-3-fatty acid of rapeseed oil ('999) for the fish oil of '063 and '206 in the pet food composition of '999. One of ordinary skill in the art would recognize that fish oil has a high content of omega-3-fatty acid, and that it is

known to include fish oil in pet foods to treat diseases. One of ordinary skill in the art would be motivated to combine the teachings of '999 and '063 or '206 since both teach that fish oil included in a pet food composition has beneficial effects for decreasing inflammation and allergic response. All teach including omega-3-fatty acids in the pet food compositions provide nutritional and health benefit and it is within the purview of the skilled artisan to substitute one known omega fatty acid for another with a reasonable expectation of success.

Claims 48-53, 55 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs et al., WO 02/15719 ('719) in view of JP 408038063 ('063) or US 2001/0051206 ('206).

The instant claims are described above.

- '719 discloses a method of treatment which comprises administering an effective amount of the composition which contains a lipid source including omega-3 fatty acids and whey protein (both intestinal mucosa function promoters according to applicant) to improve, promote, maintain intestinal function and mucins a patient or companion animal (abstract, claims 1-2 and 14-20, pg. 6 lines 5-10; pg. 12 lines 3-21). Example 4 teaches a nutritional supplement comprising whey protein and probiotic bacteria. '719 teaches that the nature of whey protein and the fact that it is capable of being easily digested, the composition has a beneficial effect in patients with limited appetite due illness, surgery, chronic gastritis, etc (pg. 4, line 31-pg. 5, line 6), and that the addition of a probiotic micro-organism provides

the advantage of restoring the natural balance of the intestinal flora following antibiotic therapy (pg. 6, lines 7-10) (according to the limitations of claims 48-50 and 55).

- '719 also teaches including a prebiotic (claim 13, pg. 5, lines 27-30) (according to the limitations of claims 49-51).
- '719 teaches omega-3-fatty acids of including the oils of rapeseed, canola, soy, hazelnut, etc (pg. 8, lines 15-24).
- '719 teaches including taurine and vitamins (claim 12, pg. 5, lines 18-25; pg. 6, lines 27-29) (according to the limitations of claims 49-53).
- '719 teaches a nutritional supplement comprising whey protein and omega-3 fatty acids (abstract, claims 1-2) (according to the limitations of claims 55 and 58-60).
- '719 does not teach omega fatty acids derived from fish oil, but does teach a pet food composition comprising omega 3:6 fatty acid content ratio of about 5:1 to about 10:1 (abstract).
- '063 teaches a pet food composition with omega 3:6 fatty acids ration of 3:1 to 10:1 preferably 5:1 to 7.5:1, and preferably fish oil (abstract).
- '206 teaches a pet food composition including omega fatty acids such as flaxseed and fish oil with a ratio of 5:1 of omega 3:6 fatty acids (abstract, Example 1 and Table 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a known omega-3-fatty acid of rapeseed oil ('719) for the fish oil of '063 and '206 in the pet food composition of '719. One of ordinary skill in the art

would recognize that fish oil has a high content of omega-3-fatty acid, and that it is known to include fish oil in pet foods to treat diseases. One of ordinary skill in the art would be motivated to combine the teachings of '719 and '063 or '206 since both teach that fish oil included in a pet food composition in an amount of 5:1 ratio of omega 3:6 fatty acid has beneficial effects for decreasing inflammation and allergic response. All teach including omega fatty acids in a 5:1 ratio in the pet food compositions provide nutritional and health benefit and it is within the purview of the skilled artisan to substitute one known omega-3-fatty acid for another with a reasonable expectation of success.

Response to Arguments

Applicant's arguments with respect to claims 48-53, 55 and 58-60 have been considered but are moot in view of the new grounds of rejection necessitated by applicants' amendments. Applicants argued that '999 or '719 in view of '206 or '063 does not teach a pancreatic promoter such as pancreatic extract, however the instant specification Example 2 a preferred pancreatic promoter exemplified is taurine.

Conclusions

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)272-6175. The examiner can normally be reached on M-F, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bethany Barham
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/Michael P Woodward/
Supervisory Patent Examiner, Art Unit 1615